JUN 0 5 1997



MEDICAID DRUG REBATE PROGRAM Release No. 29

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All Participating Drug Manufacturers

NOTE: The following item clarifies the information on the BP and AMP for PBMs provided in the Medicaid Drug Rebate Program Release No. 28.

Best Price (BP) and Average Manufacturer Price (AMP) Calculations For Pharmacy Benefit Managers (PBMs)

Previously, PBMs were instrumental in establishing and managing drug formularies for third party customers. Now, manufacturers have developed a myriad of arrangements whereby specific discounts and other chargebacks or rebates are paid to the PBM which, in turn, passes these on to the purchaser. Where PBM's subsequently adjust drug prices by applying discounts, chargebacks or rebates, these price adjustments should be included within the best price calculations. In other words, where the effect on the manufacturer for using the PBM is to adjust actual drug prices at the wholesale or retail level of trade, such adjustments need to be recognized in best price calculations.

To the extent manufacturers are offering PBMs lower drug prices at the wholesale or retail level of trade, these lower prices should be recognized in the best price calculations. Best price is generally based on the lowest price available to any entity except those excluded under the statute or rebate agreement. Therefore, where the use of the PBM by manufacturers establishes lower prices, these lower prices should be reflected in best price calculations. However, we do acknowledge that there are many PBM/manufacturer arrangements and that only those that adjust actual drug prices will be captured in best price calculations.

We generally consider drug prices to PBMs as having no effect on the AMP calculations unless the PBM is acting as a wholesaler as defined in the rebate agreement.

ADDITIONAL GUIDANCE ON AVERAGE MANUFACTURER PRICE (AMP) CALCULATIONS

On occasion, manufacturers advise us that revisions or recalculations to their pricing data are necessary. Most often, these situations occur when a manufacturer discovers that the pricing data reported to us may have been incorrectly calculated based on the improper inclusion or exclusion of certain sales. To assist manufacturers in determining the appropriateness of the AMP calculations or proposed recalculations, we are providing the attached chart as a supplement to previous instructions on the This additional information does not impose calculation of AMP. any new requirements on manufacturers and no action is necessary by manufacturers that are not revising or recalculating pricing Essentially, the information on the chart is a compilation of instructions previously provided in earlier releases. Further, the information on the chart does not supersede requirements in the rebate agreement or in section 1927 of the Social Security Act.

In Manufacturer Release Number 14, dated December 21, 1994, we advised all manufacturers of the proper procedure to follow in submitting revised or recalculated AMPs. As a reminder, all proposed recalculations based on revised methodologies of AMPs must first be submitted to us for our review, along with the

methodologies used to originally calculate the reported AMPs and the revised methodologies used for the proposed recalculations. Additionally, where possible, we request the manufacturer to provide an estimate of the magnitude of the proposed changes. Of course, adequate documentation must be maintained to support the calculations and be made available to us upon our request. The Department of Health and Human Services' Office of Inspector General has begun reviews of manufacturer pricing data and documentation must be maintained by manufacturers to support the pricing data.

In no case should a manufacturer report recalculated URAs to states or adjust rebate payments based on recalculated AMPs without our prior approval. Again, we ask those manufacturers that are contemplating revisions to their pricing data to refer to manufacturer release number 14.

T-BILL RATES - NEW FORMAT

With this release, please note that the T-Bill rates are listed on three pages, 3 columns per page and include rates from the first week of January, 1991 through the present. We have been emphasizing the fact that, where possible, every attempt should be made to resolve 1991 and 1992 disputes as quickly as possible. To this end, we thought it would be helpful to have every T-Bill rate from the start of the drug rebate program to the present available for quick reference when resolving these disputes and calculating interest. Beginning with the next release, only page 3 will be included. When that is filled up, only page 4 will be included, etc. All T-Bill rates will continue to be included on the Medicaid Drug Rebate portion of the HCFA home page.

OTHER ATTACHMENTS

Copies of the topic index and the complete listing of the 90-day treasury bill auction rates for the period of January 7, 1991 through the present are attached.

Page 4 - Medicaid Drug Rebate Program

Please remember to direct your drug rebate questions to a staff member on the listing we provided with release number 18 or section "O" of the operations guide.

Judith D. Moore Acting Director Medicaid Bureau

3 Attachments

cc:

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid

AVERAGE MANUFACTURER PRICE/BEST PRICE CALCULATIONS

D REBATES ADDITIONAL INFO!	DUE	Note 1 Sales discussed in this chart may be affected by	subsequent sales to an excluded/included entity	No for AMP/BP purposes.	Yes	Yes Note 1 - Yes, if the drug is used in the outpatient	pharmacy and the Hospital bills Medicaid for	Yes reimbursement for dispensing the outpatient	drug. Otherwise, no.	No	NO	Note 2 - Yes, except for sales to wholesalers	which can be identified with adequate	No documentation as being subsequently sold	to any of the excluded sales categories.	No		Yes	Additional note - All pricing adjustments affecting	No the price of any sales must be taken into account	if the sales were included in the calculation of	AMP/BP.		Yes			COTON
INCI LIDED	IN BP	Yes		Yes	Yes	Yes		Yes		S N	S S			No		No		Yes		S N				Yes			Note 2
INCLUDED	IN AMP	No		No	No	Yes		Yes		No No	No			No		No		Yes		N _o				Yes		100	Note 2
SAIRS		Direct Hospital Sales		HMOs (Drugs Dispensed Under Capitated Rate)	HMOs (Drugs Dispensed Under Fee-for-Service)	Mail Order Pharmacy		Retail Pharmacy		PHS Covered Entities	State-Funded Only - Pharmacy Assistance	Programs		VA/DOD Excluded Sales		Federal Supply Schedule Sales	· · · · · · · · · · · · · · · · · · ·	Nursing Home Primary/Contract Pharmacy Sales		Sales to Other Manufacturers Who	Repackage/Relabel Under the Purchaser's NDC		Sales to Other Manufacturers Who Act as	Wholesalers and Do Not Repackage/Relabel	Under the Purchaser's NDC		Wholestore